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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,673	09/05/2003	Amos Nussinovitch	85189-5100	2188

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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10/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,673	Applicant(s) NUSSINOVITCH ET AL.	
	Examiner David M. Naff	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE of 8/8/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-16,18-40,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 22-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7-16,18-21,43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/8/07 has been entered.

An amendment of 7/5/07 after final rejection amended claims 1, 2, 5, 21 and 43, and canceled claims 4, 6, 41 and 42.

A supplemental amendment of 8/8/07 amended claim 1 and added new claim 44.

Claims in the application are 1, 2, 5, 7-16, 18-40, 43 and 44.

Claims 22-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 3/29/06.

Claims examined on the merits are 1, 2, 5, 7-16, 18-21, 43 and 44.

Claim Objections

Claim 44 is objected to because of the following informalities: in line 4, "preserves" should be --- preserve ---. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

5 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10 Claims 1, 2, 5, 7-16, 18-21, 43 and 44 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the
15 time the application was filed, had possession of the claimed invention.

Support is not found in the specification a porosity of "about 87 +/-SD 1.5% to about 94 +/-SD 0.1% in claim 1 (bridging lines 2 and 3). The porosity disclosed in the specification (page 20, lines 4-6) is
20 describing specific beads containing specific components, and does not support any beads within the scope of the present claims having the porosity described for the specific beads.

Support is not found in the specification for the thickness being that of walls separating pores as required in claim 43. The
25 specification discloses the thickness being bead wall thickness, and the specification is unclear as to the part of the bead that is the wall thickness.

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Support is not found in the specification for porosity sufficient to preserve the viability of the entrapped microorganisms and to enable controlled release of the microorganisms as required in claim 44 (lines 4-5). The page and lines of the specification should be pointed out where the porosity is disclosed preserving viability of the microorganisms and enabling controlled release of the microorganisms.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

10 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15 Claims 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20 Claim 43 is unclear by requiring a thickness of walls separating pores since the thickness disclosed in the specification is not disclosed as being a thickness of walls separating pores. The specification discloses the thickness being bead wall thickness, and the specification is unclear as to the part of the bead that is the wall thickness.

25 In claim 44, the porosity that preserves viability of the microorganisms and enables controlled release of the microorganisms is

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uncertain since the specification fails to disclose specific porosity that functions to preserve viability and enable controlled release.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, 7-13, 16, 18-21, 43 and 44 are rejected under 35
5 U.S.C. 103(a) as being unpatentable over Marosi et al (4,818,530) in view of Sudoma (4,956,295) and Daggett et al (4,879,239), and if necessary in further view of Vedamuthu et al (5,919,695).

The claims are drawn to porous solid cellular hydrocolloid carriers comprising freeze-dried hydrocolloid beads having a desired
10 porosity comprising viable microorganisms entrapped therein, and the freeze-dried beads have a residual moisture content of no more than 20%.

Marois et al disclose dried alginate pellets containing a fungi such as *Trichoderma viride* (Example 13) that controls soilborne
15 diseases. The pellets have been dried to about 10% moisture (col 5, line 13). The pellets can have a diameter of 1-2 mm (col 4, line 18). Fillers and other additives can be present in the pellets (col 4, lines 1-10).

Sudoma discloses (col 5, lines 20-25) freeze-drying in the
20 presence of a cryoprotectant to provide a storage stable bacteria composition without being refrigerated (col 3, line 24).

Daggett et al disclose using glycerol as a cryoprotectant when freeze-drying microorganisms (col 1, line 52).

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Vedamuthu et al disclose using glycerol in an amount of 10% as a cryoprotectant when freezing and holding bacteria at -80°C (col 5, lines 24-37).

When producing the dried beads of Marois et al, it would have been obvious to use freeze-drying and a cryoprotectant as suggested by Sudoma and Daggett et al to obtain dried beads stable during storage without refrigeration. If needed, Vedamuthu et al would have further suggested the use of a cryoprotectant when freezing bacteria. The pellets of Marois et al will inherently be porous, and maintain viability during freeze-drying and storage as required by claims 1 and 44 after freeze-drying in the presence of a cryoprotectant as suggested by Sudoma and Daggett et al. When using freeze-drying and a cryoprotectant, the pellets of Marois et al will inherently have a porosity in the range of claim 1, and as required by claim 44 to preserve viability and enable controlled release, and a wall thickness for walls between pores in the range of claim 43. The conditions of dependent claims are inherent in the pellets of Marois et al, or would have been obvious from conditions disclosed by Marois et al, Sudoma and Daggett et al. The use glycerol as the cryoprotectant as in claims 5 and 44 would have been obvious from Daggett et al using glycerol as a cryoprotectant, and if needed Vedamuthu et al using glycerol as a cryoprotectant. If needed, Vedamuthu et al would have suggested an amount of glycerol in the range of 10-50% as in claims 5 and 44 from disclosing the use of 10% glycerol.

Response to Arguments

Applicant's arguments filed 7/5/07 have been fully considered but they are not persuasive.

Freeze-drying the pellets of Marosi et al in the presence of a cryoprotectant as suggested by Sudoma and Daggett et al will inherently result in beads having a porosity, and being capable of retaining activity as claimed. Sudoma and Daggett et al clearly disclose freeze-drying in the presence of a cryoprotectant to provide a storage stable bacteria, and do not suggest only storing without refrigeration. Furthermore, the microorganism activity maintained as recited in claim 1 is that capable of being maintained if the beads are stored for the specified time and temperature recited in the claim. The claim does not require a positive step of storing the beads for 12-36 months at -18°C and maintaining an activity of not less than 50-95% during the storage. The cryoprotectants of Sudoma and Daggett et al would have been expected to protect and maintain the activity of bacteria in a hydrocolloid gel during freeze-drying and storage similar to when the bacteria are not in the gel. The use of glycerol as a cryoprotectant is suggested by Daggett et al, and if needed Vedamuthu et al.

It is granted Marois et al may not disclose a porous carrier. However, after freeze-drying as suggested by Sudoma and Daggett et al, the pellets of Marois et al will inherently be porous. The drying of Marois et al being optional does not mean that drying should be avoided or not carried out.

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While Sudoma may freeze-dry a mixture of pre-dried bacteria, non-moisture absorbing organic salt carrier and water absorbing silica gel absorbent, Sudoma does not disclose that the particular mixture used is required for freeze-drying to dry the cells for storage stability.

5 As disclosed by Sudoma, the bacteria are freeze-dried before mixing with the other components (col 4, lines 65-68, col 5, lines 1-25, and step (b) of claim 4 (col 10)). Additionally, Daggett et al freeze-dry bacteria without using a mixture as disclosed by Sudoma.

Claim Rejections - 35 USC § 103

10 Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 2, 5, 7-13, 16, 18-21, 43 and 44 above, and further in view of Elliott et al (5,030,562) or Pusey et al (4,764,371).

The claims require the microorganisms in the beads to be bacteria
15 capable of controlling plant pathogens.

Elliott et al and Pusey et al disclose bacteria that control plant pathogens.

When freeze-drying the pellets of Marois et al as suggested by Sudoma as set forth above, it would have been obvious to replace the
20 fungi in the pellets of Marois et al that control a soilborne disease with bacteria that control a plant pathogen as suggested by Elliott et al or Pusey et al to obtain the function of the bacteria for controlling a plant pathogen.

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Response to Arguments

It is granted Elliott et al or Pusey et al do not disclose the porous freeze-dried beads of the present invention. However, Marois et al, Sudoma and Daggett et al applied above suggest the porous
5 freeze-dried beads of the invention. Elliott et al and Pusey et al are not relied on for suggesting porous-freeze dried beads.

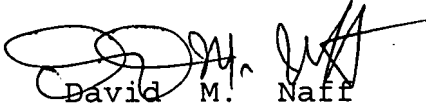
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
10 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or
15 proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


David M. Naff
Primary Examiner
Art Unit 1657

DMN

15 10/9/07